

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

)
)
) MDL NO. 1456
) CIVIL ACTION NO. 01-12257-PBS
)

THIS DOCUMENT RELATES TO
ALL ACTIONS

) Hon. Patti B. Saris
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**MEMORANDUM OF ASTRAZENECA PHARMACEUTICALS LP CONCERNING
GENERAL PRINCIPLES OF AND REQUIREMENTS FOR NOTICE**

This Court certified a class action against Defendant AstraZeneca Pharmaceuticals LP (“AstraZeneca”) on January 30, 2006. In the four months between that date and last week when the Court raised this issue of notice on its own, Plaintiffs did nothing to provide this Court with a notice plan. Then, on May 25, 2006, the Plaintiffs requested on an expedited basis that this Court set a hearing for June 5, 2006 to consider the notice to be given in this class action. On May 31, 2006, Plaintiffs filed a motion, brief, and two affidavits (aggregating 190 pages of materials and exhibits). None of the papers filed by Plaintiffs address the important Due Process and Federal Rule of Civil Procedure 23 concerns implicated here. Indeed, Plaintiffs’ filing is largely without legal citation and seeks to foist upon the Court and the Defendants an ill-conceived program with the implicit threat that time is short. Defendant AstraZeneca respectfully requests that this Court adjourn the expedited hearing scheduled for June 5, 2006 to provide an adequate opportunity for full briefing, and to allow the Court to contemplate the significant issues presented by, but not mentioned in, Plaintiffs’ perfunctory submission.

The scope, content, clarity and manner of Plaintiffs’ proposed notice — by publication only to consumer class members — raise serious Due Process concerns. AstraZeneca submits

this memorandum of the general principles and requirements that apply to this Court's evaluation of Plaintiffs' Motion to demonstrate for the Court the serious issues overlooked by Plaintiffs; it would be dangerous to give these issues short shrift because of Plaintiffs' strategic decision to wait until the eleventh hour. The Court must consider these principles against the notice proposed by Plaintiffs, and more importantly, against what Plaintiffs have failed to include in the proposed notice program.

POINT I

THE TOUCHSTONES FOR EVALUATING ANY AND ALL NOTICE TO ABSENT PERSONS ARE MULLANE AND EISEN

In Mullane v. Central Hanover Bank & Trust Co., the Supreme Court emphasized the bedrock principle that “[a]n elementary and fundamental requirement of due process in any proceeding which is to be accorded finality is notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.” 339 U.S. 306, 314 (1950). Utilizing Mullane and the Federal Rule of Civil Procedure 23(c)(2), the Supreme Court in Eisen v. Carlisle & Jacquelin, the seminal case on class action notification requirements, held that Rule 23(c)(2) includes an “unambiguous requirement” that “[i]ndividual notice must be sent to all class members whose names and addresses may be ascertained through reasonable effort.” 417 U.S. 156, 173, 176 (1974).

Accordingly, when notice is a person's due, as it is in any (b)(3) class action, the means and methods proposed must be evaluated against what “one desirous of actually informing the absentee might reasonably adopt to accomplish” actual notice. Mullane, 339 U.S. at 315 (“[P]rocess which is a mere gesture is not due process”). The vital importance of Mullane

continues—it was central to the Supreme Court’s reversal for insufficient notice only one month ago. Jones v. Flowers, 126 S. Ct. 1708, 1715 (2006). Accordingly, Mullane and Eisen continue to guide the First Circuit’s analysis of class actions. See e.g., Kerkhof v. MCI Worldcom Inc., 282 F.3d 44, 55 (1st Cir. 2002); Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 297-98 (1st Cir. 2000) (same); Le Beau v. Spirito, 703 F.2d 639, 644 (1st Cir. 1983) (quoting Mullane on constitutional requirements for notice); Puerto Rico Tel. Co. v. Telecommunications Regulatory Bd., 189 F.3d 1, 19 (1st Cir. 1999) (same); In re Compact Disc Minimum Advertised Price Antitrust Litig., 215 F.R.D. 197, 203 (D. Mass. 2003) (same).

POINT II

THE NOTICE REQUIRED TO BE GIVEN TO ABSENT CLASS MEMBERS BY RULE 23 NECESSITATES THAT THIS COURT ASSURE THAT CLASS MEMBERS GET ACTUAL INDIVIDUAL NOTICE IF POSSIBLE

A. This Court is charged with protecting the interests of absent class members in receiving actual, individualized notice, especially where, as here, both the class counsel and the class representatives do not propose to give absent class members any individual notice.

- This Court has the ultimate responsibility to guard the rights of absentee class members by ensuring that this most elementary and fundamental requirement of due process is protected. Mindful of the gravity of the due process values at stake and “for the protection of the members of the class,” Rule 23(d) gives the Court authority to require the parties to provide the notice “in the manner as the court may direct.” FED. R. CIV. P. 23(d).
- “Responsibility for compliance is placed primarily upon the active participants in the lawsuit, especially upon counsel for the class, for, in addition to the normal obligations of an officer of the court, and as counsel to parties to the litigation, class action counsel possess, in a very real sense, fiduciary obligations to those not before the court. *The ultimate responsibility of course is committed to the district court in whom, as the guardian of the rights of the absentees, is vested broad administrative, as well as adjudicative, power.*” Greenfield v. Villager Indus., Inc., 483 F.2d 824, 831-832 (3d Cir. 1973) (emphasis added).

- The rationale behind the mandatory notice requirement of 23(b)(3) is that otherwise, it would be constitutionally impermissible to give the judgment binding effect against absent class members. 7AA Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, FEDERAL PRACTICE AND PROCEDURE, § 1786 at 492-93 (3d ed. 2005).
- The Court has a vested interest in ensuring notice is adequate in order to preserve the binding nature of the class action and avoid subsequent litigation. An absent class member who does not receive adequate notice and was therefore denied the opportunity to opt out may challenge the binding effect of the judgment. See e.g., Twigg v. Sears, Roebuck & Co., 153 F.3d 1222 (11th Cir. 1988) (finding claim preclusion could not be applied where the language of the class action notice was insufficient to notify the present plaintiff that claims like his were being litigated in the action).

B. Rule 23 requires that actual notice be mailed to the last known address of absent class members.

- Federal Rule of Civil Procedure 23(c)(2)(b) provides that, for classes certified under Rule 23(b)(3), class notice is required and must be “the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort.” FED. R. CIV. P. 23(c)(2)(B).
- In Eisen v. Carlisle & Jacquelin, the seminal case on class notification requirements, the Supreme Court held that Rule 23(c)(2) includes an “unambiguous requirement” that “[i]ndividual notice must be sent to all class members whose names and addresses may be ascertained through reasonable effort.” 417 U.S. 156, 173, 176 (1974); see also Amchem Prods. Inc. v. Windsor, 521 U.S. 591, 617 (1997) (individual notice is mandatory in (b)(3) actions and the requirement may not be relaxed based on high cost.)
- Accord, Pickett v. IBP, Inc., No. 96-A-1103-N, 2001 U.S. Dist. LEXIS 22453 (M.D. Ala. Dec. 21, 2001); R.K. Peil v. National Semiconductor Corp., No. 77-4244, 1986 U.S. Dist. LEXIS 19014 (E.D. Pa. Oct. 16, 1986); In re Nissan Motor Corp. Antitrust Litig., 552 F.2d 1088, 1098-99 (5th Cir. 1977).

C. Published Notice is a fiction, and not a substitute for actual, individualized notice.

- In Mullane the Supreme Court stated, “It would be idle to pretend that publication alone . . . is a reliable means of acquainting interested parties of the fact that their rights are before the courts. . . . In weighing its sufficiency on the basis of equivalence with actual notice, we are unable to regard this as more than a feint.” Mullane, 339 U.S. at 315.

- “We have before indicated in reference to notice by publication that, ‘Great caution should be used not to let fiction deny the fair play that can be secured only by a pretty close adhesion to fact.’” Mullane, 339 U.S. at 320 (quoting McDoland v. Mabee, 243 U.S. 90, 91 (1917)).
- In Eisen the Supreme Court noted the general rule it articulated in Schroeder v. City of New York, that “notice by publication had long been recognized as a poor substitute for actual notice and that its justification was ‘difficult at best.’” Eisen, 417 U.S. at 175 (quoting Schroeder v. City of New York, 371 U.S. 208, 213 (1962)).
- It would be error for a Court to rely solely on notice by publication. Silber v. Mabon, 18 F.3d 1449, 1453 (9th Cir. 1994).

POINT III

PLAINTIFFS ARE REQUIRED TO GET THE NAMES AND ADDRESSES OF ABSENT CLASS MEMBERS FROM THIRD PARTIES AND GIVE ACTUAL NOTICE, BY MAIL, TO THE LAST KNOWN ADDRESS, REGARDLESS OF THE COST OR TIME

A. Plaintiffs are required to obtain, by subpoena or otherwise, names and addresses of absent class members from third parties.

- When a source exists from which the actual names of absentee class members are able to be ascertained, courts require substantial effort to gather them. Eisen, 417 U.S. at 175; see also 3 Alba Conte & Herbert Newberg, NEWBERG ON CLASS ACTIONS § 8:3, 171 (4th ed. 2005) (noting that when names and addresses of class members are known, “individual notice is clearly the best notice practicable within the meaning of Rule 23(c)(2) and prior Supreme Court precedent”).
- The effort required must be commensurate with the size of the class the plaintiffs seek to bind by the outcome of this litigation and with the gravity of the due process values at stake. See Eisen, 417 U.S. at 175 (reasonable effort required plaintiffs to gather 2,250,000 names and addresses by comparing several million computerized records and to provide actual notice by mail to each class member so identified); In re Nissan, 552 F.2d at 1098-1100 (manual search by plaintiff for identifiable class members through 1,700,000 cards listing names and addresses of purchasers of new motor vehicles, while expensive and time-consuming, is within range of “reasonable effort” required by Eisen).

- If a third party possesses the names and addresses of class members, the plaintiff must seek the names and provide notice by mail. In R.K. Peil v. National Semiconductor Corp., a securities class action, the district court ruled that the plaintiffs could not simply contact brokerage houses and rely upon them to forward notice to beneficial owners, especially in light of the fact that some brokerage houses declined to identify beneficial purchasers due to confidentiality policies. No. 77-4244, 1986 U.S. Dist. LEXIS 19014 (E.D. Pa. Oct. 16, 1998). The district court ordered that “Plaintiff must cooperate with nominees in working out financing arrangements and resolving confidentiality issues raised by brokerage firms. This may involve cash deposits and reimbursements to nominees for their expenditures in attempting to identify class members and for forwarding class notices to beneficial owners.” Id. at *18
- If a third party refuses to cooperate, the Court may, under Rule 23(d), issue a subpoena duces tecum requiring production of information necessary for identification. Oppenheimer Fund Inc. v. Sanders, 437 U.S. 340, 354 & n.21 (1978) (“It is clear that Rule 23(d) vests power in the district court to order the plaintiff to perform the tasks necessary to send notice.”) In Peil, the district court stated that if any third parties are “unwilling to identify or notify beneficial purchasers for purposes of this class action, plaintiff shall issue subpoena duces tecum to recalcitrant nominees.” 1986 U.S. Dist. LEXIS 19014 at *18; see also In re Visa Check/ Mastermoney Antitrust Litig., No. CV-96-5238, 2002 U.S. Dist. LEXIS 23327, at *6-7 (E.D.N.Y. June 21, 2002) (district court directed plaintiffs to subpoena 81 financial institutions in attempt to obtain names and addresses of additional class members); Pickett v. IBP, Inc., No. 96-A-1103-N, 2001 U.S. Dist. LEXIS 22453 (M.D. Ala. Dec. 21, 2001) (court-ordered notice plan included identification of class members through state UCC filings and directed plaintiffs to subpoena information from third parties who did not cooperate); Carlough v. Amchem Products Inc., 158 F.R.D. 314 (E.D. Pa. 1993) (court ordered notice plan included identification of absentee class members through plaintiff’s contact of national and local labor unions who may have current or retired members in the plaintiff class).

B. Plaintiffs can subpoena the Centers for Medicare and Medicaid Services (“CMS”) to obtain records in the form of Explanation of Medicare Benefits (“EOMBs”) in order to identify and provide actual notice to absent class members. Furthermore, the Healthcare Insurance Portability & Accountability Act of 1996 (“HIPAA”) regulations do not bar CMS from providing the names and addresses of class members for purposes of sending notice.

- The Stipulated Protective Order Governing Confidential Health Information, entered by this Court on June 8, 2004, is a “qualified protective order” as defined

in HIPAA regulations. 45 C.F.R. § 164.512(e)(1)(v). Thus, CMS may disclose protected health information in response to an order of this court, § 164.512(e)(1)(i), or in response to a subpoena or discovery request unaccompanied by an order of the court if the party seeking the information assures CMS that it has made reasonable efforts to secure a qualified protective order that meets the requirements of § 164.512(e)(1)(v), § 164.512(e)(1)(ii)(B).

- Plaintiffs have presented no admissible evidence of efforts to gather class members names and addresses through other sources, such as private insurers.

C. The fact that ascertaining the names and addresses and giving actual mailed notice to absent class members will take time and cost plaintiffs money is irrelevant – they must do what Due Process and Rule 23 require.

- The notice requirements of Rule 23 will not be “tailored to fit the pocketbooks of particular plaintiffs” nor adapted to time constraints. Eisen, 417 U.S. at 176 (“There is nothing in Rule 23 to suggest that the notice requirements can be tailored to fit the pocketbooks of particular plaintiffs.”); see also Mullane, 339 U.S. at 318 (“Exceptions in the name of necessity do not sweep away the rule that within the limits of practicability notice must be such as is reasonably calculated to reach interested parties. Where the names and post-office addresses of those affected by a proceeding are at hand, the reasons disappear for resort to means less likely than the mails to apprise them of its pendency.”); Abelson v. Strong, No. 85-0592-S, 1987 U.S. Dist. LEXIS 7515, at *23 (D. Mass. July 30, 1987) (“[Eisen] held that due process and Rule 23(c)(2) require that absent class members receive actual notice, where that is possible, and ruled further that named plaintiffs must be willing and able to pay the costs of such notice.”).
- “The [Eisen] Court held that when class members can be identified, individual notice is mandatory, and economic obstacles will not allow recourse to the best notice practicable as a type of saving clause.” 3 Conte & Newberg, NEWBERG ON CLASS ACTIONS §8:3 at 171; 7AA Wright, Miller & Kane, § 1786 at 507 (“Thus, it is clearly settled that in Rule 23(b)(3) actions all identifiable class members must be given individual notice, despite the cost that may be involved.”).
- Time constraints do not absolve the parties of their duty to fulfill the mandates of Due Process, especially here, where Plaintiffs’ own delay has put the rights of absentee class members in jeopardy. In re Nissan Motor Corporation Antitrust Litigation involved an antitrust class action by original purchasers of Datsun vehicles. 552 F.2d at 1098-99. Defendant Nissan possessed 1.7 million Retail Delivery Report (RDR) cards, which recorded sales of Datsun vehicles for the relevant time period. Id. at 1094. The district court characterized the review of RDR cards in search of class members as a “herculean task” and an

“unnecessarily time consuming and burdensome process.” Id. at 1096. Defendants brought interlocutory appeal of the district court’s notice order pursuant to the collateral order doctrine, 28 U.S.C. § 1291. Id. at 1094. The Fifth Circuit reversed the district court, holding that Plaintiffs must, at their own expense, compile a list of the absentee class members’ names and addresses from examination of defendants’ RDR cards. Id. at 1098-1100. The Court stated: “While the mechanical process of examining the cards may prove to be expensive and time-consuming, the individual right of absentee class members to due process makes the cost and effort reasonable.” Id. at 1100.

D. Class Counsel and the Class Representatives sought these positions and promised the Court, and the absent class members, they would do all that Rule 23 required.

- Plaintiffs moved for certification of this expansive class and represented to this Court that they were prepared to take on the responsibilities of class representative. Now, on the eve of trial, Plaintiffs’ last minute attempt to avoid their obligation to provide the best notice practicable by claiming that the task is too time-consuming or expensive should fall on deaf ears. In re Nissan, 52 F.2d at 1102 (internal citation omitted) (“Upon commencing a class action, the class representatives must be prepared to accept the concomitant responsibility of identifying absentee class members as well as paying the costs of their individual notice.”).

POINT IV

THE CONTENT OF THE COURT’S NOTICE MUST BE CLEAR, BALANCED, ACCURATE

A. Notice comes from the Court.

- Rule 23(c)(2) states that “the court” is to direct notice to the class members. “[T]he initial notice under subdivision (c)(2) should come from and bear the imprimatur of the court itself.” 7AA Wright, Miller & Kane, FEDERAL PRACTICE AND PROCEDURE, § 1788 at 531.
- The Rule 23 Advisory Committee noted that ““This mandatory notice pursuant to subdivision (c)(2) . . . is designed to fulfill requirements of due process to which the class action procedure is of course subject.”” § 8:4 (4th ed. 2002) (citing Advisory Committee Notes to Fed. R. Civ. P. 23).

B. The law requires the Court to ensure that the content of the notice adequately apprises the absentee class members of the issues in the suit and the steps they can take to remain or opt-out.

- The court must conduct a case-by-case inquiry to determine whether the content of the publication notice is adequate to protect the rights of absentee class members. West Virginia v. Chas. Pfizer & Co., 44 F.2d 1079, 1091 (2d Cir. 1971).
- “Surely the best notice practicable under the circumstances cannot stop with . . . generalities. It must also contain an adequate description of the proceedings written in objective, neutral terms, that, insofar as possible, may be understood by the average absentee class member. . . . Not only must the substantive claims be adequately described but the notice must also contain information reasonably necessary to make a decision to remain a class member and be bound by the final judgment or opt out of the action.” Twigg, 153 F.3d at 1227 (citing Nissan, 552 F.2d at 1103-05).
- The best practicable notice to absentee class members must contain an adequate description of the proceedings written in objective, neutral terms that, insofar as possible, may be understood by the average absentee class member. Nissan, 552 F.2d at 1088.
- Accord, 7AA Wright, Miller & Kane, FEDERAL PRACTICE AND PROCEDURE, § 1787.

C. The law also requires that notice be written in clear, balanced, neutral terms.

- “The district court is responsible for ensuring that class notice meets the requirements of objectivity and specificity. Class notice should avoid too much legal jargon, as well as the risk of bias: ‘the notice content should be neutral in tone . . . conveying the required information in such a way as to not influence the readers’ decision to assert a claim.’ . . . Notice should not provide indication of the merits of the claims; however, it should inform class members of the suit’s progress.” In re Auto. Refinishing Paint Antitrust Litig., No. 1426, 2003 U.S. Dist. LEXIS 7692 (E.D. Pa. April 10, 2003) (quoting Conte & Newberg, NEWBERG ON CLASS ACTIONS § 8:31 (4th ed. 2002)).
- Accord, Schaefer v. Overland Express Family of Funds, 169 F.R.D. 124, 131 (D. Cal. 1996); Payton v. Abbott Labs, 86 F.R.D. 351, 352 (D. Mass. 1980) (district court denied proposed form of notice because it was not sufficiently complete or neutral. The court emphasized that the notice should be neutral and objective in tone, and should neither promote nor discourage the assertion of claims); Nissan, 552 F.2d at 1104 (noting that the best practicable notice to absentee class

members must contain an adequate description of the proceedings written in objective, neutral terms that, insofar as possible, may be understood by the average absentee class member); Lamb v. United Sec. Life Co., 59 F.R.D. 25, 42 (S.D. Iowa 1972) (same).

D. Plaintiffs' proposed notice fails to comply with these standards in many respects, including, among others:

- Plaintiffs' notice groups all Defendants and all drugs in a single notice, despite the fact that AstraZeneca is the only Defendant with a trial scheduled to begin in several months.
- Plaintiffs fail to present an accurate and balanced description of the case. Indeed, Plaintiffs omit entirely any description of Defendants' defenses or the procedural posture of the case.
- In fact, the proposed publication notice does not provide notice at all, but rather directs potential class members to affirmatively request notice materials.
- Plaintiffs media plan makes no effort to target specifically the Zoladex user profile.
- These are just a few of the many significant issues raised by Plaintiffs' proposed notice, which the Court must carefully evaluate pursuant to the principles described above.

POINT V

THE COURT MUST HAVE A FACTUAL RECORD FOR ANY NOTICE DETERMINATIONS

A. Factual Basis

- This Court must make a factual determination regarding what is the "best notice practicable under the circumstances" and what constitutes "reasonable effort." In re Visa Check/ Mastermoney Antitrust Litig., 2002 U.S. Dist. LEXIS 23327, at *6-7 (district court entered findings of fact regarding plaintiff's obligation to identify and mail notice to class members). In re "Agent Orange" Prod. Liab. Litig., 100 F.R.D. 718, 729 (S.D.N.Y. 1983) (Weinstein, J.) ("What is 'the best notice practicable under the circumstances' and what constitutes 'reasonable effort' is a determination of fact to be made in the individual litigation.").
- Plaintiffs have made no effort to identify the names and addresses of Class 1 members. Nor have Plaintiffs proffered admissible evidence for their absolute failure in this regard, but only the conclusory and uncited statement in a four page

brief that “[t]he names of Class 1 members are not readily identifiable.” (Plaintiffs’ Motion for Notice at 3).

- Accordingly, this Court has no basis upon which to make the factual determination that notice by publication satisfies the mandates of due process and Rule 23.

B. Where, as here, the adequacy of the proposed notice program and the propriety of the form of notice are disputed, the Court can and should hold an evidentiary hearing.

- The district court in Eisen held an evidentiary hearing to determine how many class members could be identified with reasonable effort. 52 F.R.D. 253 (1971) rev’d, 417 U.S. 156, 177 (holding that the court may not conduct a preliminary merits inquiry for purpose of apportioning notice costs). Based upon the parties’ access to computer listings, the district court found that the names and addresses of 2,250,000 class members could be identified with reasonable effort. Id. at 257-58; see also Laskey v. Int’l Union, UAW, 683 F.2d 954, 956 (6th Cir. 1981) (evidentiary hearing conducted); In re Visa Check/ Mastermoney Antitrust Litig., 2002 U.S. Dist. LEXIS 23327, 6-7 (S.D.N.Y. 2002) (district court entered findings of fact regarding plaintiff’s obligation to identify and mail notice to class members).

CONCLUSION

For all of the foregoing reasons and in light of the considerable interests at stake the Court should allow additional time to fully consider a more appropriate notice plan for this litigation.

Dated: Boston, MA
June 2, 2006

Respectfully Submitted,

By: /s/ Lucy Fowler

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 2, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Lucy Fowler
Lucy Fowler